COVID-19 Therapeutics Bi-Weekly Update
June 27th, 2022

Process and logistics updates

NEW Direct Order Request (DOR) Process

VDH is transitioning from its current COVID-19 Therapeutics ordering process that takes place in VaxMaX to a new process that takes place in the Health Partner Order Portal (HPoP). This change occurred on Friday, 6/24/2022 at 4:00 PM Eastern. All providers who need to request therapeutics will be required to order through the portal using the updated process. For your convenience, an ordering link to HPOP is scheduled to be made accessible from the VDH Homepage by 6/27/22.

Please note this new DOR for COVID-19 **Therapeutics** will not affect the process for ordering COVID-19 vaccines. Vaccines will still be ordered in VaxMax and Therapeutics will be ordered in HPoP.

VDH hosted a webinar on 6/23 to go over the Direct Order Request (DOR) process. The recording for this webinar can be accessed here. For further instructions on the DOR process, please use the HPoP Job Aid.

Redistribution

Great news! VDH now can redistribute therapeutics within our commonwealth. This new capability enables providers to assist each other by transferring therapeutics in the field. This cross-leveling allows us to stretch supply within Virginia in times of scarcity and allows us to avoid waste due to expiry of potentially lifesaving therapeutics.

Any providers wishing to make their therapeutics available for transfer can do so by clicking the link "Redistribute Excess Therapeutics" on the VDH home page beginning Tuesday, June 28, 2022 Monday, June 27, 2022. The VDH Therapeutics team will prioritize these available therapeutics before pulling from federal supplies whenever it is advantageous to do so.

Listen to the Redistribution webinar here. The Redistribution discussion starts at 8:55.

Pending Decision On EVUSHELD Expiration Extension

Several lots of EVUSHELD are rapidly approaching their posted expiration date. The Food and Drug Administration (FDA) is currently deciding on whether to extend the shelf life of EVUSHELD. We have received guidance from the Office of the Assistant Secretary for Preparedness and Response to inform providers to maintain the EVUSHELD currently in the field in anticipation of the pending decision on expiration extension. The decision is expected to occur sometime in July 2022.

Summer Holiday Schedule - threshold notifications

Holiday Planning: Threshold Notifications and Delivery

- Threshold determinations and notifications will not occur on the noted federal holidays below. Federal observance of these holidays occurs on Mondays. As a result, threshold determinations and notifications will occur on the following Tuesday.
- Deliveries will occur as scheduled on all Fridays prior to the corresponding Federal Holiday. If you wish to hold orders on Friday, please contact Amerisource Bergen at C19therapies@amerisourcebergen.com.

Holiday Observance	Threshold Determination/Notification	Deliveries
Juneteenth (June 20th)	Tuesday, June 21st	As scheduled; no change
Independence Day (July 4th)	Tuesday, July 5th	Paused on July 4th Resume on July 5th
Labor Day (September 5th)	Tuesday, September 6th	Paused on September 5th Resume on September 6th
Columbus Day (October 10th)	Tuesday, October 11th	As scheduled; no change
Christmas (December 26th)	Tuesday, December 26th	Paused on December 26th Resume on December 27th

Upcoming July 6 HPOP Enhancements

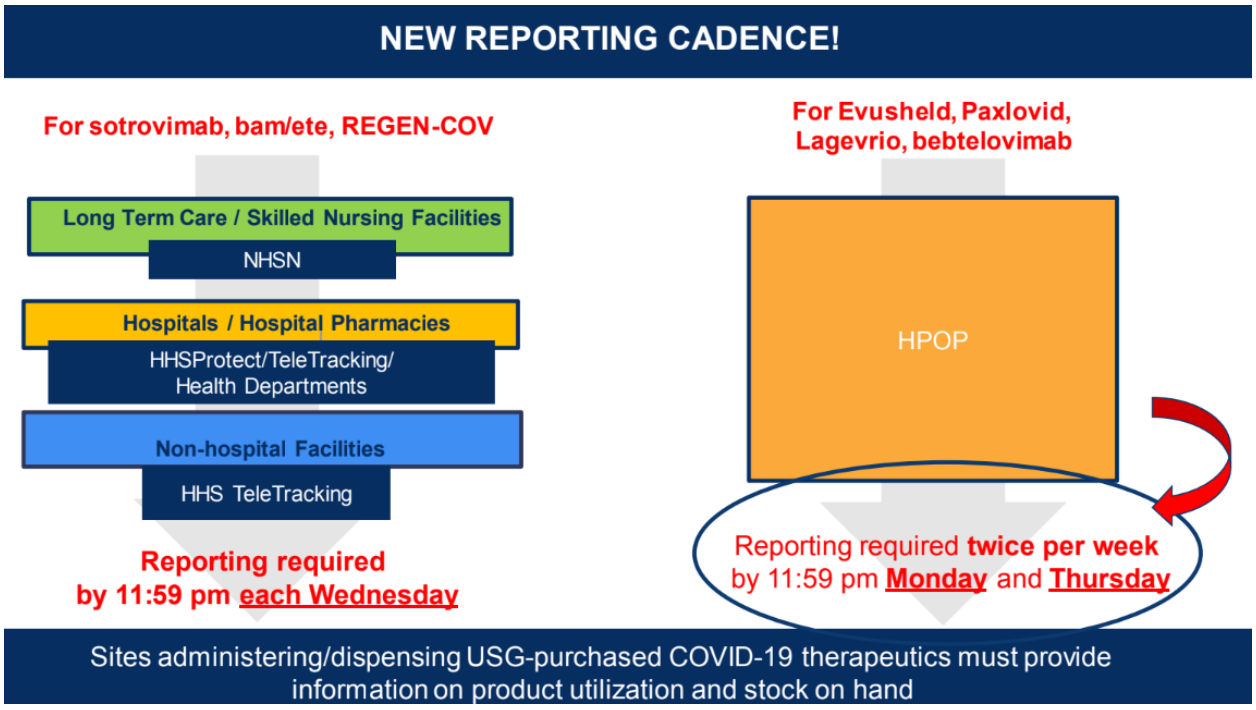
ASPR Unclassified / For Public Distribution

Upcoming July 6 HPOP Enhancements

- Add Provider field to Provider Search options
- Email a copy of the agreed to attestation agreement when the user signed it
- Coming to Project Management will be a section that includes details of each sprint release
- Add the capability when entering Stock on Hand for Therapeutics
- Add an event in the log that partners can see of time/date and user each time a user verifies the address and hours information
- An email will generate to the help email on file when a provider leaves feedback directed to partner

Reporting update!

Great news! Based on feedback from providers on the difficulty of reporting daily, **new required reporting cadence will be only bi-weekly on Monday and Thursday by 11:59 PM EST.**



Reminder: A note about Bebtelovimab supply

Oral antiviral supply continues to be ample; however, bebtelovimab has a finite and therefore somewhat limited supply due to limited funding from the federal government. It is important for providers to be stewards of this medication and reserve it for cases where paxlovid is not appropriate or contraindicated. The federal government is working on a solution for a short term bridge, with hopes of extending the supply past mid-summer.

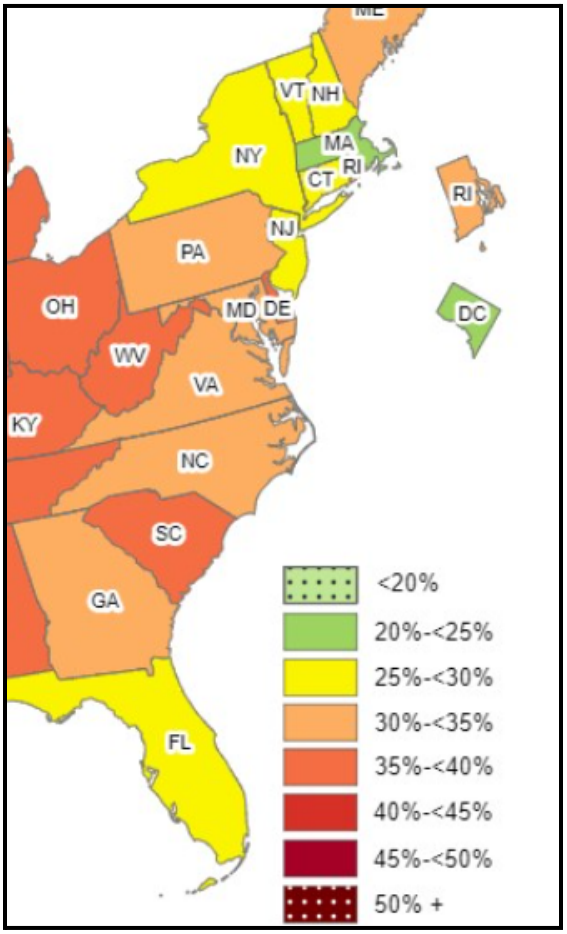
Therapeutics in the News

Pfizer gives up on Paxlovid in less vulnerable COVID-19 patients after data fail to impress

Pfizer has stopped enrolling patients into the EPIC-SR trial, which has been underway to evaluate patients who are at standard-risk (as opposed to those categorized as high-risk for progression to severe COVID-19) due to a lack of efficacy demonstrated thus far. The treatment was not effective in reducing symptoms in this patient population. Read more here.

Study Results: COVID-19 Rebound after Paxlovid

A retrospective EHR data review study from a large healthcare system in California suggested that hospitalizations and ED encounters related to SARS-CoV-2 infection were very low. Paxlovid continues to be recommended for early treatment in eligible persons infected with COVID-19. Review the MMWR here.



**Percentage of the population in VA considered obese*

Spotlight on Obesity (source: CDC)

Per the CDC, obese patients are at a higher risk for hospitalization, need intensive care, and/or require a ventilator as a result from Covid-19 infection. Impairment in immune function and decreased lung capacity is associated with obesity. Data shows that from the beginning of the pandemic through November 18, 2020, an estimated 30.2% of Covid-19 hospitalizations were attributed to obesity.

Unfortunately, this risk factor also adversely affects children. An analysis of Covid-19 events in

patients 18 years and younger with obesity revealed a 3.07 times increased risk for hospitalization and a 1.42 times increased risk for severe illness when hospitalized. As with adults, severe illness means ICU admission, requirement of invasive mechanical ventilation, and/or death.

Obesity disproportionately affects non-Hispanic Black adults and Hispanic adults.

Per the current EUAs for OAVs and MAB, obesity can be a stand-alone risk factor that may qualify a patient for receipt of Covid-19 therapeutics.

Allocation data

Total Allocations to Therapeutic Administration Sites (6/08/2022 – 6/22/2022):

Therapeutic (mAB & OAV*)	Central	Eastern	Northern	Northwest	Southwest	Total
Bebtelovimab	230	190	200	285	245	**1150**
Evusheld	168	48	96	336	24	**672**
Lagevrio (Molnupiravir)	24	24	24	48	24	**144**
Paxlovid	20	120	480	180	0	**800**
Renal Paxlovid	30	10	20	5	10	**75**

*Oral Antiviral numbers presented do not include those allocated to Community Pharmacy Enhanced Services Network. These Oral Antiviral courses were bulk ordered and distribution to individual site locations is managed by respective Federal Retail Pharmacy Therapeutic Program (FRPTP) partners, VDH does not have visibility of course distribution to each region.
*Please reference the Outpatient Therapeutic Portfolio- Jurisdiction Allocations for more detail.

VDH resources

Therapeutics locator tool:

Find where to access therapeutics here.

Link to sign up for the newsletter:

Did your colleague share this newsletter with you, and you'd like to sign up to receive it directly? Do you know of a colleague that would benefit from receiving information on therapeutics from VDH? Click here to sign up!

VDH Therapeutics Website for Healthcare Providers

Check out the VDH Therapeutics webpage here. Reach out to COVID19Therapeutics@vdh.virginia.gov for questions, comments, or feedback on information you'd like to see.

COVID-19 Therapeutics Webinars and Open Forum Calls

- VDH is continuing to facilitate webinars and open forums monthly.
  See below for links to ***register***!

  June 29 Open Forum:
  https://vdh.zoom.us/webinar/register/WN_mbW4dOYARqaNTOM2LyzMjQ

Additional resources and education

AZ Evusheld educational webinar for clinicians:
Please reach out if you are interested but unable to attend on the dates/times listed as we may be able to schedule additional sessions with Astra Zeneca!

PROTECTION ONBOARD:

A CLINICAL APPROACH TO PREVENTING COVID-19 IN AT-RISK PATIENTS

Monday, June 27, 2022
AZ MSL
3:00 PM EST
https://bit.ly/20136385

Tuesday, June 28, 2022
AZ MSL
2:00 PM EST
https://bit.ly/20136387

Tuesday, June 28, 2022
LIVE NATIONAL BROADCAST
Dr. Calabrese (Cleveland Clinic) & Dr. Kumar (Medstar Georgetown University Hospital)
7:00 PM EST I 10:00 PM EST
https://event.webcasts.com/starthere.jsp?ei=1553243&tp_key=55a598cc3c

Wednesday, June 29, 2022
AZ MSL
12:00 PM EST
https://bit.ly/20136365

Thursday, June 30, 2022
AZ MSL
1:00 PM EST
https://bit.ly/20136376

Clinical reminder: What therapeutics are currently authorized?

There are currently 5 therapeutics authorized. **Other therapeutics should not be prescribed or administered at this time.**

Pre-exposure prophylaxis: EVUSHELD
Treatment: Paxlovid (first line oral antiviral)
Molnupiravir (second line oral antiviral)
Bebtelovimab (monoclonal antibody)
Remdesivir (IV antiviral)

These therapeutics are currently deauthorized by the FDA, and should not be ordered, dispensed, or administered:

REGEN-COV (Casirivimab and Imdevimab)
Sotrovimab
Bamlanivimab and Etesevimab ("Bam-ete")

Available Therapeutics

	Type	Classification	Use	How is it given?	When is it given?
Prevention	Tixagevimab / cilgavimab (EVUSHELD)	Monoclonal antibody for pre-exposure prophylaxis	• For those NOT infected with COVID-19 • No known exposure to COVID-19 AND • Moderate to severe immune system compromise or who may not mount an adequate immune response to vaccination	By injection into muscle	When NOT currently infected with COVID-19 AND no known recent exposure
Treatment	Bebtelovimab	Monoclonal antibody	For treatment of mild-moderate COVID-19	By infusion into a vein	Within 7 days of symptoms starting
	Remdesivir (Veklury)	IV Antiviral	For treatment of COVID-19 (inpatient or outpatient)	By infusion into a vein	Within 7 days of symptoms starting
	Nirmatrelvir/ritonavir (Paxlovid)	Oral Antiviral	For treatment of mild-moderate COVID-19	By oral tablet	Within 5 days of symptoms starting
	Molnupiravir (Lagevrio)				

Therapeutics Efficacy

Therapeutics	Risk reduction of hospitalization or death
EVUSHELD	83% (risk reduction of developing COVID)
Paxlovid	88-90%
Remdesivir	87%
Bebtelovimab	40% (relative reduction in viral load)
Lagevrio (Molnupiravir)	30%